K101178
p1/3

JUN 2 9 2010

510(k) Summary
As required by 21 CFR §807.92(c)

Submitter

510(k) Owner:	Intel Corporation
Address:	1900 Prairie City Road, FM7-197, Folsom, CA 95630
Telephone:	(916) 356-1109
Contact Person:	Maureen Glynn
Date Prepared:	April 23rd, 2010

Device Information

Trade Name:	Modification to Intel® Health Guide PHS6000
Common Name:	Remote Patient Monitoring System
Classification Name:	Transmitters and Receivers, Physiological Signal, Radiofrequency (21 CFR 870.2910, Product Code DRG)

Substantial Equivalence is claimed to the following device:
Intel Corporation's Intel® Health Guide PHS6000 (**K080798 & K083115**)

Device Description

The Intel® Health Guide PHS6000 is a communication tool that allows caregivers to remotely access vital sign measurements of patients at home. It collects measurements captured on commercially available wireless or tethered medical devices designed for home use, stores and displays the collected information on the LCD screen, and transmits the information to a secure host server. Caregivers can review the transmitted information and select education and reminders for patients using a caregiver software interface to the host server. Patients can review the stored vital sign measurement information and receive educational and motivational content from caregivers. Patients can also optionally engage in video conferences with caregivers and answer the caregivers' questions by participating in surveys.

510(k) Notification Submission – Special 510(k)
Modification to Intel® Health Guide PHS6000

The Intel® Health Guide PHS6000 system consists of the:

(1) Intel® Health Guide PHS6000 hardware:

The physical component of the Intel® Health Guide PHS6000 is an electronic device contained in a plastic enclosure with a touch screen, video camera with privacy screen, microphones, speakers and a reminder light which is mounted into the top of the case. On the back of the device is a power socket, a headphone socket, a Broadband (high-speed) internet socket for connection to a broadband network. The device has medical device sockets for connection to specific physiological monitors, and may optionally have a phone socket for modem connection to a standard phone line.

(2) Intel® Health Guide software application:

The software application captures, stores, and transmits information to a secure website via a standard telephone line or a LAN/WAN connection.

(3) Intel® Care Management Suite software application:

The application allows caregivers to review patient vital signs on the secure website. The Intel® Care Management Suite allows for predefining upper and lower limits and, when either limit is exceeded, the system emails and/or pages the caregiver.

(4) Processor software application:

The processor software application manages the interface between the Intel® Health Guide PHS6000 software application and the secure website.

The Intel® Health Guide PHS6000 is not intended for diagnosis or as a substitute for medical care, and it is not intended to provide real time data. It is made available to patients when time-critical care is not required. The device is contraindicated for patients requiring direct medical supervision or emergency intervention. The device is intended for patients who are willing and capable of managing its use. Clinical judgment and experience by a caregiver are required to check and interpret the information delivered.

Indications for Use

The Intel® Health Guide PHS6000 is a communication tool that allows caregivers to remotely access vital sign measurements of patients at home. It collects measurements captured on commercially available wireless or tethered medical devices designed for home use, stores and displays the collected information on the LCD screen, and transmits the information to a secure host server. Caregivers can review the transmitted information and select education and reminders for patients using a caregiver software interface to the host server. Patients can review the stored vital sign measurement information and receive educational and motivational content from caregivers. Patients can also optionally engage in video conferences with caregivers and answer the caregivers' questions by participating in surveys.

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Technological Characteristics

The Intel® Health Guide PHS6000 is substantially equivalent to the predicate device in terms of data collection software functionality, operating system for the patient device, communication method of patient device with central server, types of sensors which can be interfaced to the patient device, implementation method of collecting data from sensors, sensor software, connectivity, communication protocol, power source, and display method.

Safety and Efficacy

The Intel® Health Guide PHS6000 does not rely on an assessment of clinical performance data. The device conforms to FDA's recognized consensus standards and relies on its conformity to demonstrate the safety and efficacy. The device introduces no new questions concerning the safety or efficacy and is, therefore, substantially equivalent to the predicate device.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Room –WO66-G609
Silver Spring, MD 20993-0002

JUN 29 2010

Intel Corporation
c/o Ms. Maureen Glynn
Director of Regulatory Affairs
1900 Prairie City Road
Folsom, CA 95630

Re: K101178
Trade/Device Name: Modification to Intel® Health Guide PHS6000
Regulatory Number: 21 CFR 870.2910
Regulation Name: Radiofrequency Physiological Signal Transmitter and Receiver
Regulatory Class: II (two)
Product Code: 74 DRG
Dated: May 20, 2010
Received: June 8, 2010

Dear Ms. Glynn:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

M. J. Hillebrenner

for Bram D. Zuckerman, M.D.
Director
Division of Cardiovascular Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

K101178

Indications for Use:

510(k) Number: K101178

Device Name: Modification to Intel® Health Guide PHS6000

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Prescription Use X AND/OR Over-The-Counter Use _____
(Part 21 CFR 801 Subpart D) (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

M. A. Hillebrenner

(Division Sign-Off)
Division of Cardiovascular Devices

510(k) Number K101178